Institutional Readiness Levels:

Site assessment questionnaire

Produced by Northern Alliance ATTC.

The Institutional Readiness questionnaire created by NA-ATTC is for use by NHS Clinical Sites to self-assess their own Institutional Readiness for adoption of ATMPs, both through clinical trials and licensed medicines. The toolkit contains the following documents:

(A) Introduction and Background

(B) Work Instructions for Site IR Self - Assessment

(C) Institutional Readiness for ATMP Questionnaire

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(A) Introduction and Background

It is recognised that successful adoption of ATMPs requires NHS Trusts / Boards to be able to adapt their skills, processes and practices at an institutional level. Institutional Readiness (IR) has been suggested as a means of assessing the capacity of an institution to adopt new technologies. Within the context of healthcare, IR can be defined as; "*Whether, and if so, how far, an organisation needs to adapt to embrace a new technology*". Gardner, Webster and Barry (2018) discuss the concept of IR in depth and examine the challenges of implementing regenerative medicine (RM) therapies within hospitals and clinics. They also highlight dynamics within existing healthcare systems that will present both hindrances and affordances for the implementation of new RM technologies within hospitals and clinics [1].

An IR Working Group consisting of stakeholders from each of the NA-ATTC clinical sites was established to develop a tool to assess IR based on previous work in the technology industry [1]. Using the table of criteria for assessing the IR of clinical delivery sites for RM therapies within the paper as a basis [1], and following a workshop with support from Prof Andrew Webster [1], NA-ATTC developed a questionnaire for its clinical delivery sites to self-assess their own IR for Advanced Therapies. The group agreed criteria against which IR was assessed which illustrated the breadth of IR that is necessary for successful adoption of ATMPs. IR was self-assessed by clinical sites for four exemplar products that were chosen to illustrate IR across the different classifications of ATMP.

This user-validated tool has been developed for use by clinical sites with aspirations to deliver ATMPs. This work was led by Ewan Morrison, Director of Pharmacy (NHS National Services Scotland) and Ruaridh Buchan, Senior Clinical Trials Pharmacist (NHS Lothian) on behalf of the Northern Alliance Advanced Therapies Treatment Centre programme, in collaboration with Newcastle Hospitals NHS Trust, NHS Greater Glasgow and Clyde, Leeds Teaching Hospitals NHS Trust and NHS Lothian.

Reference: [1] Gardner J, Webster A, Barry J. Anticipating the clinical adoption of regenerative medicine: building institutional readiness in the UK. Regenerative medicine. 2018 Jan;13(1):29-39.

(B) Work Instructions for Site IR Self - Assessment Exercise

1. Identify coordinator(s) within the NHS institution who will be responsible for identifying and convening the assessment panel, collating and interpreting the completed questionnaire and summarising key actions following assessment.

2. Identify key stakeholders within NHS institution with expertise in clinical delivery or professional interest in each class of ATMP to form an assessment panel. Suggested stakeholders include, but are not limited to:
    - Stem cell laboratories
    - Appropriate clinical delivery team
    - Directorate/Trust/Board management
    - Ward managers
    - Pharmacy
    - Support departments (e.g. ITU, Neurology, Apheresis)
    - Research & Development departments
    - HTA Licence Holder Designated Individual

- Quality management teams
- Financial management teams

3. Supporting documentation should be highlighted including selected Summary of Product Characteristics from the relevant class of products. The four classes of ATMPs are Virus based gene therapy, Cell based gene therapy, Somatic cell therapy and Tissue engineered products. These documents should be circulated to the assessment panel ahead of meeting in order for members to familiarise themselves with the assessment process and classes of ATMP.

4. Convene panel to assess Institutional Readiness according to the criteria listed in the questionnaire against the four ATMP classes or ATMP class(es) of interest. Each criterion should be rated as follows:
    - Red – not started at site
    - Amber – in process of being developed
    - Green – developed and evidenced.

5. It is important to document, with supporting comments, the rationale for assigning criteria a colour as this facilitates interpretation of the completed questionnaire.

6. The coordinator should analyse the completed questionnaire taking into account supporting comments in order to identify areas of good practice, areas where work is being undertaken and areas where further work is required.

7. It is recommended that the questionnaire is completed at regular intervals to assess progress within the NHS institution.

Other suggested resources include;

Advanced Therapies NHS Readiness Toolkit	https://www.theattcnetwork.co.uk/advanced-therapies-nhs-readiness-toolkit
Pharmacy oversight and supervision requirement for preparation of licensed ATMPs	https://www.sps.nhs.uk/articles/pharmacy-oversight-and-supervision-requirements-for-preparation-of-licensed-atmps/
Requirements for Governance and Preparation of Gene Therapy	https://www.sps.nhs.uk/articles/requirements-for-governance-preparation-of-gene-therapy-pan-uk-pharmacy-working-group-for-atmps/
Regulatory Requirement for export of ATMP starting materials	https://www.sps.nhs.uk/articles/regulatory-requirements-for-export-of-atmp-starting-materials-pan-uk-pharmacy-working-group-on-atmps/
Pharmacy institutional readiness for Marketed CAR-T Therapy	https://www.sps.nhs.uk/articles/pharmacy-institutional-readiness-for-marketed-car-t-therapy-guidance-for-chief-pharmacists/
Generic Autologous ATMP Clinical Flow Chart	https://www.theattcnetwork.co.uk/wp-content/uploads/2020/01/Generic-Autologous-Patient-Pathway-V1.3-19.12.19-1.pdf
Generic Allogenic ATMP Clinical Flow Chart	https://www.theattcnetwork.co.uk/wp-content/uploads/2020/01/Generic-Allogeneic-V1.4-09.05.19.pdf

(C) Institutional Readiness for ATMP Questionnaire

Tissue Engineered/Cell Based Gene/Somatic Cell/Virus Based Gene

By product class in an NHS Trust/Board

NHS Trust or Board:	Date:	Completed by:

Criteria relating to the ATMP technology or technique	Criteria relating to the potential site of clinical delivery	Red Amber Green	Comments in support of assessment
Target indication for the ATMP	Existing expertise in delivering ATMP within class?		
	Operational capacity to treat expected patient cohort?		
	Opportunities for patient / public involvement & collaboration?		
Complexity of intervention	Logistical clinical coordination - planning, procurement, production and distribution (within shelf life) for each individual patient?		
	Appropriate clinical infrastructure for administering treatments and supportive treatments?		
	Reactive and flexible structures are in place to allow staff training as required?		
Governance	Clear governance structures exist and can be evidenced for clinical trial and/or licensed medicines usage		

Perceptions of ATMP technology	Goal alignment of front-line clinicians, administrators, managers and other stakeholders? e.g. CAR-T – growth of product would require more ITU beds.		
	Does the ATMP have high profile across the institution/geography?		
Place and mode of harvesting and packaging of starting materials and preparation of ATMP	Access to relevant Pharmacy expertise? i.e. has Pharmacy readiness assessment been completed?		
	Are facilities, staff and systems in place for procurement of starting materials?		
	Are facilities and processes in place to receive and store products as required?		
	Are processes in place as required for product preparation?		
Quality	Are appropriate Quality Assurance staff in place? e.g. governance structure in place for supporting the use of specialist clinical trial products out of specification?		
	Are appropriate Quality Management Systems in place?		
Can costs and clinical outcomes be reliably monitored?	Clinical Trials		
Resource and expertise is available for data-collection infrastructure?	Licensed products including early access to medicines		

Funding **Resource and expertise available to secure appropriate funding and cost pathways [capital and revenue]?**	Clinical trials		
	Licensed products including early access to medicines		
Others	Is there a mechanism to complete and approve local business case(s) through Trust/Board governance channels?		

Assessment Measures for each section

Red – Not started	In comments section describe whether it is intended to prepare for any or all of the ATMP class and any timescales that are currently being discussed.
Amber – In process of being developed	In comments section indicate what stage preparations are at in relation to each ATMP class, what plans are in place for attaining readiness and projected timescales.
Green – In place and evidenced	In comments section indicate which ATMP classes are ready to be delivered and share any learning which may benefit the other Hospitals.